

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Robert A. Herrmann et al.  
Application No.: Unassigned  
Date Filed: Filed Herewith  
Title: DIFFERENTIAL DELIVERY OF NITRIC OXIDE  
Group Art: 1615  
Examiner: Unassigned  
Docket: 00-0193 D1

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INFORMATION DISCLOSURE STATEMENT (IDS)

Mail Stop Patent  
Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22231-1450

SIR:

In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO/SB/08 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office.

I. COPIES

- a. ☐ A legible copy of (i) each U.S. and foreign patents; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith.
- b. ☒ Any patents, publications or other information which are listed on PTO/SB/08 which are not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120:

U.S. Serial Number  
09/765,131

U.S. Filing Date  
01/18/2001

II. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

- a. ☒ Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required).
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

III. ☐ CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.

Filing Date

Art Unit

**FEES**

- IV. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b): (check one box)
- a. ☒ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is required.
  - b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
  - c. ☐ before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
  - d. ☐ before the mailing date of a first Office Action after the filing of a request for continued examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- V. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(c): (check one box)  
before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (See 37 C.F.R. §1.97(c)).
- a. ☐ No statement; therefore, charge deposit account 50-1047 the fee set forth in 37 C.F.R. §1.17(p).
  - b. ☐ See the statement below. No fee is required.
- VI. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(d):  
on or before payment of the issue fee and is accompanied by the following:
- 1) a statement under 37 C.F.R. §1.97(e) as provided below; and
  - 2) charge deposit account 50-1047 the petition fee set forth in §1.17(p).
- VII. ☐ STATEMENT UNDER 37 C.F.R. §1.97(e) (check only one box, if applicable)  
The undersigned hereby states that
- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of IDS; or
  - b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
  - c. ☐ some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.
- VIII. PAYMENT OF FEES
- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the above-identified fee(s).
  - ☐ Please charge Deposit Account No. 50-1047 in the amount of \$180.00 for the above-indicated fee(s).
  - ☒ If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 50-1047.
  - ☐ Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted,  
Mayer Fortkort & Williams, PC



Kevin J. Park  
Attorney for Applicant  
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Tel. 908-518-7700

Mayer Fortkort & Williams, PC  
Customer Number 27774

Enclosures: ☒ PTO/SB/08  
☐ References  
☐ Foreign Search Report  
☐ Other:

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I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Mail Stop Patent, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on 3/11/04.

Marjorie Scariati  
(Printed name of Person Mailing Correspondence)

Marjorie Scariati  
(Signature)

# INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)

00-0193-D1

Application Number

Unassigned

Applicant(s)

Robert A. Herrmann, et al.

Filing Date

Filed Herewith

Group Art Unit

1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	4,466,914	8/21/84	Hazen et al.	260	239	
	2	5,116,861	5/26/92	Goto et al.	514	427	
	3	5,583,101	12/10/96	Stamler et al.	514	2	
	4	5,665,077	9/9/97	Rosen et al.	604	266	
	5	5,676,963	10/14/97	Keefer et al.	424	423	
	6	5,718,892	2/17/98	Keefer et al.	424	78.27	
	7	5,770,645	6/23/98	Stamler et al.	524	419	
	8	5,814,666	9/29/98	Green et al.	514	611	
	9	5,852,058	12/22/98	Cooke et al.	514	564	
	10	5,861,168	1/19/99	Cooke et al.	424	424	
	11	5,994,444	11/30/99	Trescony et al.	524	429	

## FOREIGN PATENT DOCUMENTS

REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	S.C. Askew, et al., "Chemical Mechanisms Underlying the Vasocilator and Platelet Anti-Aggregating Properties of S-Nitroso-N-acetyl-DL-pencillamine and S-Nitrosoglutathione", Bioorganic & Medicinal Chemistry, Vol. 3, No. 1, pp. 1-9 (1995).
2	S.K. Pulfer, et al., "Incorporation of Nitric Oxide-Releasing Crosslinked Polyethyleneimine Microspheres Into Vascular Grafts," Journal of Biomedical Material Res. 1997, 37:182-189.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box. FORM PTO/SB/08

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	Unassigned
				Filing Date	Filed Herewith
				First Named Inventor	Robert A. Herrmann et al.
				Group Art Unit	1615
				Examiner Name	Unassigned
				Attorney Docket Number	00-0193 D1
Sheet	2	of	4		

[illegible]

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	T
		Office <sup>3</sup>	Number <sup>4</sup>	Class/Subclass			
	1.	WO	97/16983	A23L 1/305	Board of Trustees of the Leland Stanford Junior University	May 15, 1997	
	2.	WO	98/06389	A61K 31/195	Board of Trustees of the Leland Stanford Junior University	February 19, 1998	
	3.	WO	00/62614	A01N 37/12	Nitrosystems, Inc.	October 26, 2000	
	4.	EP	0546 796 A1	A61K 31/195	Ajinomoto Co., Inc.	June 16, 1993	
	5	WO	99/30716	A61K 31/535		06-24-1999	
	6	WO	96/35416	A61K 31/095		11-14-1996	

Examiner Signature		Date Considered	
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicant(s)

Robert A. Herrmann, et al.

Filing Date

Filed Herewith

Group Art Unit

1-61-5-000

EXAMINER INITIAL	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
3	K. Bohl, et al., "Nitric Oxide Producing Materials: A Potential Therapy For Thrombosis and Restenosis," Proceedings of the International Symposium on Control. Rel. Bioact. Mater. 1999, 26:56-57.
4	K.A. Mowery, et al., "Preparation and Characterization of Hydrophobic Polymeric Films that are Thromboresistant via Nitric Oxide Release," Biomaterials 2000; 21:9-21.
5	B. Halliwell, et al., "Nitric Oxide and Peroxynitrite. The Ugly, the Uglier and the Not So Good," Free Rad. Res. 1999; Vol. 31:651-669.
6	D. Salvemini, et al., "Evidence of Peroxynitrite Involvement in the Carageenan-Induced Rat Paw Edema," Eur. Journal of Pharmacology 1996; 303 (3):217-220.
7	A.H. Cross, et al., "A Catalyst of Peroxynitrite Decomposition Inhibits Murine Experimental Autoimmune Encephalomyelitis," Journal of Neuroimmunology 2000; 107 (1):21-28.
8	S. Ratnam, et al., "The Regulation of Superoxide Generation and Nitric Oxide Synthesis by C-reactive Protein," Immunology 1998; 94(4):560-568.
9	Y. Xia, et al., "Superoxide and Peroxynitrite Generation From Inducible Nitric Oxide Synthase in Macrophages," Proceedings of the National Academy of Science USA 1997; 94(13):6954-6958.
10	M. Sandoval, et al., "Peroxynitrite-Induced Apoptosis In Epithelial (T84) and Macrophage (RAW 264.7) Cell Lines: Effect of Legume-Derived Polyphenols (Phytolens), Nitric Oxide 1997; 1(6):476-483.
11	M. Schoenfisch, et al., "Improving the Thromboresistivity of Chemical Sensors Via Nitric Oxide Release: Fabrication and In Vivo Evaluation of Nitric-Oxide-Releasing-Oxygen-Sensing Catheters," Anal Chem 2000; 72(6):1119-1126.
12	L. Liaudet, et al., "Biology of Nitric Oxide Signaling," Critical Care Medicine 2000; 28 (4 Suppl):N37-N52.
13	F.C. Tanner, et al., "Nitric Oxide Modulates Expression of Cell Cycle Regulatory Proteins. A Cytostatic Strategy for Inhibition of Human Vascular Smooth Muscle Cell Proliferation," Circulation 2000; 101:1982-1989.
14	L. Rossig, et al., "Nitric Oxide Downregulates MKP-3 Levels: Involvement in Endothelial Cell Protection From Apoptosis," Journal of Cell Biology 2000.
EXAMINER	DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				Filing Date	Filed Herewith
				First Named Inventor	Robert A. Herrmann et al.
				Group Art Unit	1615
Examiner Name	Unassigned				
Sheet	4	of	4	Attorney Docket Number	00-0193 D1

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	15	David R. Janero et al., "Nitric Oxide and Postangioplasty Restenosis: Pathological Correlates and Therapeutic Potential," <i>Free Radical Biology &amp; Medicine</i> , Vol. 29, no. 12 (2000), pp. 1199-1221.	
	16	.Bohl, K. et al., "Nitric Oxide-Generating Polymers Reduce Platelet Adhesion and Smooth Muscle Cell Proliferation," <i>Biomaterials</i> , Vol. 21 (2000), pp. 2273-2278.	
	17	Ganaha, F. et al., "Efficient Inhibition of In-Stent Restenosis by Controlled Hybrid Stent-based Local Release of Nitric Oxide," Abstract. <i>Circulation</i> , Vol. 104, No. 17, Supplement, October 23, 2001, p. II.506.	

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